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March 24, 2005

Food and Drug Administration
Dockets Management Branch
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Petition to the Food and Drug Administration to change the labeling and take further action to address the association of Viagra (Sildenafil) use and increased STD transmission, including HIV infection. (No. 2004P-0351)

Dear Sir or Madam:

Pfizer Inc submits these comments in response to the petition (No. 2004P-0351) filed by Jeffrey Klausner MD, MPH, regarding Pfizer's erectile dysfunction medication Viagra® (sildenafil citrate). Dr. Klausner's petition requests a change in labeling and other sources of information about Viagra, in response to an observed association between illegal and improper Viagra® use and the transmission of sexually transmitted diseases (STDs) among populations of men who have sex with men. For the reasons expressed below, Pfizer believes the actions requested by the petition are unwarranted and inappropriate. Thus, Dr. Klausner's petition should be denied.

Pfizer agrees that the increasing incidence of STDs, including Human Immunodeficiency Virus (HIV), in men who have sex with other men (MSM) is of

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concern. However, there are no clinical data to support the petition's suggestion that Viagra® (sildenafil citrate) use increases STD transmission in this or any other population. There are many factors that contribute to increased rates of STDs and HIV in the MSM population. It has been established that high risk sexual behavior patterns and lack of condom use are the most likely factors contributing to STD and HIV infection.¹ No data exist, however, that point to Viagra® use as a causal factor of STD transmission.

Although the petition cites several studies of Viagra® use in MSM, these studies do not support the Petitioners' proposed label change. The subgroup surveyed in these references has multiple factors that increase the risk for transmission of STDs and HIV. These include high risk sexual practices (including unprotected anal sex), the use of intravenous drugs (particularly methamphetamine), seeking sex on the internet, and sex with multiple partners. These risk factors have not been controlled for in the cited studies and therefore no conclusions can be drawn.

In the absence of any such data, there is no clinical foundation for the Petitioners' request for a Viagra® label change including the statement that: "The use of Viagra® increases the risk for new sexually transmitted diseases, including HIV infection". Multiple partners and lack of condom use are the drivers for increased incidence of STD and HIV transmission within populations. The Viagra® label already states: "The use of Viagra® offers no protection against sexually transmitted diseases. Counseling of patients about the protective measures necessary to guard against sexually transmitted diseases, including Human Immunodeficiency Virus (HIV), may be considered." Moreover, this precaution is included within the balance of all direct to consumer (DTC) material for Viagra®.

The following are examples of the language used in Viagra DTC campaigns:

"Viagra does not protect you from diseases that can be passed through sex. Make sure to protect yourself and your partner."

"Remember to protect yourself and your partner from sexually transmitted diseases."

In addition to providing the above-quoted precautions in its Viagra® advertising, Pfizer supports a number of programs promoting sexual health awareness and improved sexual health within the community. Pfizer has demonstrated leadership in a broad range of health literacy and educational initiatives across all populations at risk for STDs. As a responsible corporate citizen, Pfizer is working with consultants and the National Coalition of STD Directors to address this national concern. In addition Pfizer has also supported various programs specifically targeted at MSMs.

Pfizer agrees that specific education should be targeted towards this population in order to decrease high risk sexual behavior. The label change proposed by the petition, however, would not be effective to address these issues.

It is believed that the MSM population cited in the references rarely obtains sildenafil under the supervision of a medical practitioner through a prescription. The drug they use is often obtained from a friend, the internet, the street or from illegal sources. Any information Pfizer may provide through medical practitioners and product labeling is unlikely to reach this population. Therefore a change to the Viagra® (sildenafil citrate) label, even if the proposed change had a rational scientific basis, would be unlikely to have any impact on the MSM population mentioned in the petition. Pfizer also believes the proposed change in the Viagra® label would confuse and misinform the general population who are legitimately using Viagra®.

Petitioners' request that Viagra® be listed as a Schedule III drug also is unsupported. Schedule III is appropriate for substances such as ketamine that have the potential for psychological and physical dependency. There is no basis to suggest that Viagra®, with its strong safety record, has these characteristics. As discussed previously, individuals within the population cited in the petition usually acquire the Viagra® illegally (or acquire illegal sildenafil products) and therefore scheduling status would have no impact on the acquisition of the product. Schedule III status, however, would adversely affect the majority of legitimate Viagra® users who need and rely on Viagra® to treat their medical condition. Accordingly the petitioners' request for Schedule III status for Viagra® should be denied.

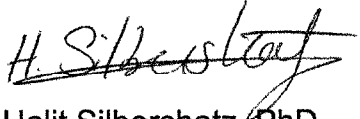
It is widely recognized that erectile dysfunction (ED) can negatively impact psychosocial functioning.² Pfizer and experts in sexual medicine have worked hard to destigmatize ED. Pfizer strongly believes that the actions suggested by Petitioners would only serve to restigmatize the condition and unnecessarily frighten (and affect the well being of) those who legitimately need Viagra®, use it appropriately and obtain it through legitimate channels.

Pfizer works hard to ensure that the appropriate patients are prescribed Viagra® (sildenafil citrate) and that these patients receive genuine Viagra®. For example, Pfizer has gone to great lengths to protect the public from the health risks and other risks associated with the illegal sale of fake or unapproved generic products claiming to be "Viagra". Pfizer's actions have included filing legal actions, working with government authorities and launching a consumer education campaign. Pfizer will continue to put effort into preventing counterfeit and illegal versions of sildenafil from possibly harming customers.

Although concerns regarding MSM and the spread of HIV are valid, these are issues that need to be addressed through targeted education of MSMs as well as

sexual health education to people in general and not through inappropriate and scientifically unsupported label changes for products.

Sincerely,

A handwritten signature in black ink, appearing to read 'H. Silbershatz', with a stylized, cursive script.

Halit Silbershatz, PhD
Director/Team Leader, US Medical Viagra
Cardiovascular, Metabolic, & Sexual Health
Pfizer Inc

References:

1. Harrison's Principles of Internal Medicine, 16th Edition. Kasper DL, Braunwald E, Fauci AS et al.
2. NIH Consensus Conference; Impotence JAMA 1993;270 (1): 83-90.